RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0690

McN
McNEIL CONSUMER P
FORT WASHING

Individual Safety Report
3031776-6-00

Page

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
Case 185 In confidence	24 yrs	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death unknown (mo/day/yr)
- ( ) life-threatening
- (x) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 02/06/98 (mo/day/yr)

5. Describe event or problem

Case # 185 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown acetaminophen product
#2

2. Dose, frequency & route used

#1 "supratherapeutic doses"
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 4 days
#2

4. Diagnosis for use (indication)

#1 unknown
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown
#2

7. Exp. date (if known)

#1 Unknown
#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (x) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE INTENT
ACIDOSIS
INFECTION
EDEMA BRAIN
LIVER FUNC ABNO
PROTHROMBIN INC
KIDNEY FAILURE
DEATH

9. Mfr. report number: 0929363A

E. Initial reporter

1. Name, address & phone #

[redacted] MD
[redacted] Centers
Suite [redacted] Avenue
[redacted]

2. Health professional? (X) Yes ( ) No

3. Occupation: physician

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0691

Individual Safety Report
3C31776-6-00

[redacted] FATALITY: 1996 [redacted]

Case Number: 185

Age:	24 yrs
Substances:	Acetaminophen
Chronicity:	Chronic
Route:	Ingestion
Reason:	Int Unknown
Pre-Hospital Arrest?	No

A 24-year-old male with a history of intravenous cocaine abuse and alcohol abuse presented with an altered mental status. It was believed that the patient was ingesting supratherapeutic doses of acetaminophen for four days but the exact amount ingested or the reason for the ingestion were unknown. At presentation the patient had an acetaminophen level of 52 mcg/ml, an aspartate aminotransferase of 14,642 IU/L, an alanine aminotransferase of 24,000, a total bilirubin of 7.6 mg/dL, a serum creatinine of 4.2 mg/dL, a blood urea nitrogen of 36 mg/dL, a serum bicarbonate of 6 mg/dL and a prothrombin time of 37.6 seconds with an international normalized ratio of 9.6. Urine toxicologic screening was positive for acetaminophen, cocaine, pseudoephedrine, diphenhydramine, phenteramine and diphenhydrol. Blood cultures from two separate sites drawn on presentation grew out *Escherichia coli* and sputum cultures grew out *Streptococcus pneumonia*. The patient was started on N-acetylcysteine (NAC) therapy Despite treatment with NAC the patient continued to deteriorate. His renal insufficiency progressed to oliguric renal failure for which he was dialyzed. His mental status continued to deteriorate and a head CT revealed cerebral edema. The patient died 6 days after admission.